

**REMARKS**

Claim 1 has been amended to require that the copolymer be loaded with a bioactive agent. Support for this amendment is found, for example, in original claim 33 which was directed to a pharmaceutical composition comprising the copolymer of claim 1 loaded with a bioactive agent. Further support for including a bioactive agent is found on pages 24-25, bridging paragraph.

New claim 42 is supported by claim 33 as originally pending. No new matter has been added and entry of the amendment is respectfully requested.

**The Rejections**

Both of the remaining rejections are made over the art.

Claims 1-14 and 16-23 were rejected as assertedly obvious over Langer, *et al.* (U.S. 6,160,084).

Applicants appreciate the understanding of the Examiner that the exemplified copolymers are not completely amorphous at human body temperature, as they have transition temperatures above 37°C, and thus the rejection for anticipation is withdrawn. However, the Examiner points out that the glass transition temperature of the hard segment can vary over a very wide range of ~30-270°C, and that the lower range of this hard segment would therefore suggest the copolymers of the claims. However, such a range would defeat the shape memory feature of the copolymers if administered to a human body. Unless the hard segment is maintained below its transition temperature, the shape memory features would be lost.

Applicants note that other uses of the shape memory of copolymers are envisioned, but the claims are now limited to delivering biologically active agents.

Column 11, lines 36, *et seq.*, of Langer recognize that a drug delivery function can be performed by the shape memory polymers. There is no discussion in the context of this section that the polymers must be completely amorphous at the temperature of the human body. Langer does not suggest this feature of the claims that the Examiner agrees distinguishes them from the exemplified copolymer. The purpose of the copolymers of Langer is, according to the description, a shape memory copolymer that can be degraded. It is apparently this degradation capability that accounts for assuming that there are therapeutic applications where bioactive agents can be contained. See, for example, column 8, lines 51-57, as well as column 3, lines 44-46.

The point is that if the claimed copolymer is to retain its shape memory characteristics when implanted, the copolymer must have at least one phase transition above body temperature when inserted into the body and encountering body temperatures. It cannot be completely amorphous because the original shape is remembered only if the copolymer is cooled to a temperature below the  $T_{\text{trans}}$  even of the soft segment. See, for example, the last portion of the Abstract and column 3, lines 37-44.

The Examiner is correct that other uses of the shape memory polymers are envisioned which permit compositions where the segments are both above their  $T_{\text{trans}}$  at human body temperature and thus amorphous. This, however, does not make the present invention obvious because the present invention is designed for delivery of a biologically active agent. To the extent that the polymers of Langer could be used by virtue of their ability to biodegrade to deliver drugs, they are no longer shape memory polymers and do not fit the description of randomly arranged hydrolyzable segments each composed of a pre-polymer A or pre-polymer B which are randomly connected to each other by multifunctional chain extenders.

Thus, to the extent that the copolymers similar to those of the invention are described, they amount to nonanalogous art which is used for different purposes. The recent decision of the Federal Circuit in *In re Klein*, 647 F3d 1343, 98 USPQ 2d 1991 (Fed. Cir. 2011) is applicable. In that case, a bird feeder with movable partition was designed to permit mixing solutions at various concentrations of sugars according to the preferences of the types of birds to be fed. Prior art was acknowledged that different birds preferred different concentrations of sugar and this was combined with documents that showed various arrangements of moveable partitions. These moveable partitions were not designed to accommodate the needs of a bird feeder. The Court concluded that this was nonanalogous art not relevant to the problem to be solved.

Here, Langer discloses a different type of polymer — namely a biodegradable polymer that could be used to deliver drugs — which does not read on the copolymers of the invention. The alternative uses of the shape memory copolymers, which are similar to the segmented polymers of the present invention, would not be capable of serving the shape memory function at temperatures which would make them amorphous at human body temperature. Langer simply does not suggest the copolymers of the invention with  $T_{\text{trans}}$  characteristics that would permit them to be amorphous under these conditions for drug delivery.

Applicants appreciate the detailed arguments of the Office as applied to various dependent claims. However, as claim 1 from which these claims depend is not obvious over the cited art, these claims are non-obvious over the art as well.

Claims 4 and 13-15 are rejected as assertedly obvious over Langer in further view of Rashkov, *et al.*, *Macromolecules* (1996) pp. 50-56. Rashkov is applicable only to the additional

limitations of these claims. As these limitations are not relied on for patentability, this basis for rejection may be withdrawn as well.

### Conclusion

The teachings of Langer demonstrate that their shape memory copolymers, which are copolymers that contain hydrolyzable segments composed of pre-polymer A or pre-polymer B as required by the claims, would need to have at least one phase transition above 37°C if they are to behave as shape memory polymers in the human body. To the extent shape memory is described for other uses, it is nonanalogous art with regard to drug delivery using the polymers of the invention. Applicants respectfully request, therefore, that claims 1-23 and 42 be passed to issue.

Should minor issues remain that could be resolved over the phone, a telephone call to the undersigned is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 313632002300.

Respectfully submitted,

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